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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/784,674	02/15/2001	Karen W. Shannon	10971464-3	3167

22878 7590 01/26/2005

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EXAMINER

MAHATAN, CHANNING

ART UNIT

PAPER NUMBER

1631

DATE MAILED: 01/26/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application N .

09/784,674

Applicant(s)

SHANNON ET AL.

Examin r

Channing S Mahatan

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 March 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-40 and 98-101 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 5, 7, 9, 15-18, 20, 21, 28, 29 and 98-101 is/are rejected.
- 7) ☒ Claim(s) 2-4, 6, 8, 10-14, 19, 22-27 and 30-40 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

APPLICANTS' ARGUMENTS

Applicants' arguments, filed 04 March 2004, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

This is a 'Non-Final' office action based upon the below rejection under 35 U.S.C. § 112 2nd Paragraph (new), clarification of the previously applied Mitsuhashi et al. (U.S. Patent Number 5,556, 749) rejection under 35 U.S.C. § 102(b), newly applied 35 U.S.C. § 103 Rejection of Mitsuhashi et al. (U.S. Patent Number 5,556, 749) taken in view of Southern et al. (U.S. Patent Number 5, 700,637).

CLAIMS UNDER EXAMINATION

Claims herein under examination are claims 1-40 and 98-101.

Claims Rejected Under 35 U.S.C. § 112 2nd Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 28 and 29 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

VAGUE AND INDEFINITE

Claim 28 and all claims dependent therefrom recite the language “poorly correlated” which is considered vague and indefinite. The above limitation implies some range of values/criteria(s) that establishes parameters to be “poorly correlated” to one another. Applicants can resolve this issue by particularly pointing out the range of values/criteria(s) which are defines a poor correlation. Clarification of the metes and bounds, via clearer claim language, is requested.

Claims Rejected Under 35 U.S.C. § 102

The rejection of claims 1, 5, 7, 9, 15, 17, 18, 20, 21, 98, and 100 are rejected under 35 U.S.C. § 102(b) as being anticipated by Mitsuhashi (U.S. Patent Number 5,556,749) are maintained for reasons of record. The following rejection is ‘Non-Final’ because the previous ‘Office Action’ (mailed 05 November 2003) failed to provide sufficient clarification of the claims being rejected.

Applicants argue Mitsuhashi et al. does not disclose “forming clusters and selecting, for a cluster, a hybridization oligonucleotide where the hybridization of a hybridization probe is predicted by the presence of a hybridization oligonucleotide in the cluster”.

Mitsuhashi et al. (U.S. Patent Number 5,556,749) discloses an oligoprobe designstation allowing a user to calculate and design specific oligonucleotide probes for DNA and mRNA hybridization procedures (instant claims 17, 18, 20, and 21; cited U.S. Patent ‘Abstract’), wherein candidate probes are analyzed for their binding specificity relative to some known set of mRNA or DNA sequences (i.e. sequence database) (Column 6, lines 31-34). Mitsuhashi et al. describe the process of probe design as follows: 1) candidate probes are selected at some or all

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the positions along a given target (instant claim 1, step (a)); 2) a melting temperature model is selected, and an accounting is made of how many false hybridizations each candidate probe will produce and what the melting temperature will be (instant claim 1, steps (b) and (c)); 3) results are presented with a unique set of tools for visualization, analysis, and selection among the candidate probes (instant claim 1, steps (d) and (e); “formation of cluster and selection therein” which is discussed further below) (Column 6, lines 34-50). The design station graphically displays of the results thereby providing the user with the ability to visualize candidate probe hybridization strengths (i.e. T_m , which is “a function of probe length and GC content Column 14, lines 24-25) and the number of false hybridizations (various sources and temperatures) for all candidate oligonucleotide probes for the target sequence (instant claims 5, 7, and 9; Column 10, lines 41-59, Column 14, lines 4-16, and Figure 4). A particular probe and species within can be selected via an adjustable (i.e. flexible length) and movable window (i.e. from start to end) along the target sequence, wherein the movable window identifies a plurality oligonucleotides probe species (i.e. subset) within a plurality of regions/clusters (formation of a cluster) and allows for the selection of individual oligonucleotides inside the particularly “windowed” region/cluster based on hybridization strength (instant claim 1 steps (d) and (e); Column 14, lines 25-42, Column 15, lines 16-60, and Figure 4). The invention runs under Microsoft Windows on IBM compatible personal computers (i.e. memory, etc.) and the results (i.e. hybridizations of probes for the target) of the invention are outputted to a graphical display (instant claims 15, 98, and 100; Column 7, lines 18-21 & 37-41, and Columns 11-12, lines 66-67 & 1-38, respectively). Thus, Mitsuhashi et al. anticipate the instantly claimed invention.

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Claims Rejected Under 35 U.S.C. § 103

The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. § 103(c) and potential 35 U.S.C. § 102(e), (f) or (g) prior art under 35 U.S.C. § 103(a).

Claims 1, 5, 7, 9, 15-18, 20, 21, and 98-101 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Mitsuhashi et al. (U.S. Patent Number 5,556,749) in view of Southern (U.S. Patent Number 5,700,637).

Mitsuhashi et al. is applied herein as indicated in the above 35 U.S.C. § 102(b) Rejection. However, Mitsuhashi et al. fails to teach the computation of probable errors (statistics) and electronically transferring the identified oligonucleotides to an oligonucleotide array.

Southern (U.S. Patent Number 5,700,637) describes an apparatus and method for analyzing polynucleotide sequences and a method of generating oligonucleotide arrays on solid support, wherein a computer (i.e. electronically transfer data) is utilized to analyze and control

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the system (instant claims 16, 99 and 101; cited U.S. Patent 'Abstract', Columns 6-9, Example 5, and claim 2).

Southern provides motivation for the combination by disclosing numerous potential applications for the novel method of analyzing nucleotide sequences (Columns 13-17, beginning on line 31). Mitsuhashi et al. provides motivation for the combination by indicating their disclosed invention is faster, more accurate, and allows the user to perform many types of analysis on the candidate probes (Column 6, lines 51-58). Thus, it would have been obvious to someone of ordinary skill in the art at the time of the invention to practice Mitsuhashi et al. (U.S. Patent Number 5,556,749) in view of Southern et al. to utilize the computer program(s) as an efficient method to design optimal oligonucleotide probe sequences based on thermodynamic hybridizability, and transferring the resultant identified oligonucleotide probes to an oligonucleotide array manufacturing system, thereby providing a faster, more accurate, and broader application for the analysis of nucleotide sequences.

OBJECTION TO CLAIMS

Claims 2-4, 6, 8, 10-14, 19, 22-27, and 30-40 objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

EXAMINER INFORMATION

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 C.F.R. § 1.6(d)). The CM1 Fax Center number is either 571-273-8300.

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Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Channing S. Mahatan whose telephone number is (571) 272-0717. The Examiner can normally be reached on M-F (8:30-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, Ph.D., can be reached on (571) 272-0718.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify Applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables Applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Examiner Initials: *CSM*

Date: *June 24, 2005*

Ardin H. Marschel 1/24/05
ARDIN H. MARSCHEL
PRIMARY EXAMINER